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Beyond Data Capture: Using REDCap™ to Facilitate Web-Based Therapeutic Intervention Research

Stacey Crane, PhD RN CPON

Post-doctoral Fellow

Indiana University School of Nursing

Indianapolis, IN

Robert Skipworth Comer, MS

Research Associate

Media Arts and Science

Indiana University- Purdue University Indianapolis

Indianapolis, IN

Andrew D. Arenson, BA

Principal Programmer / Analyst

Pervasive Technology Institute

Indiana University

Indianapolis, IN

Claire Draucker, PhD, RN, FAAN

Angela Barron McBride Professor

Indiana University School of Nursing

Indianapolis, IN

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Stacey Crane, PhD, RN, CPON, is a post-doctoral fellow and **Claire Draucker, PhD, RN, FAAN,** is the Angela Barron McBride Professor, Indiana University School of Nursing, Indianapolis, IN.

Robert Skipworth Comer, MS, is a Research Associate, Media Arts and Science, Indiana University- Purdue University Indianapolis, Indianapolis, IN.

Andrew D. Arenson, BA, is a Principal Programmer / Analyst, Pervasive Technology Institute, Indiana University, Indianapolis, IN.

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Corresponding author: Stacey Crane, PhD, RN, CPON, Indiana University School of Nursing, 600 Barnhill Dr., NU317A, Indianapolis, IN, 46202 (e-mail: cranes@iupui.edu).

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Clinical Trial Registration: Not applicable

Abstract

***Background*:** Limited guidelines to assist nurse researchers who use web-based interventions are available. Nurses must develop the supporting technology enabling participants to complete study activities and collected data while maintaining data security and participant confidentiality.

***Objectives*:** To describe how the authors used advanced Research Electronic Data Capture (REDCap™) functionality to support the data management infrastructure of an interactive, web-based therapeutic intervention.

***Methods*:** The data management infrastructure for the WISER intervention pilot study consisted of two components: a website for presentation of the intervention and participant account management and a REDCap project for data capture and storage. REDCap application programming interface (API) connected these two components using HTML links and data exchanges.

***Results*:** We completed an initial pilot study of WISER with 14 participants using the REDCap-based infrastructure. Minimal technical difficulties were encountered.

***Discussion*:** REDCap is cost-effective, readily available, and through its advanced functionality is able to facilitate confidential, secure interactions with participants, robust data management, and seamless participant progression in web-based intervention research.

***Key Words*:** REDCap; intervention research; nursing research; research infrastructure; research

Web-based interventions are gaining in popularity because they can be completed at the participants' convenience, reach a broad audience, and be scaled up easily (Mohr, Burns, Schueller, Clarke, & Klinkman, 2013; Mohr, Schueller, Montague, Burns, & Rashidi, 2014; Pagoto et al., 2016; Wantland, Portillo, Holzemer, Slaughter, & McGhee, 2004). However, significant technological development is necessary before initial pilot studies of newly developed web-based interventions can commence. Nurse researchers employing these interventions thus need to build a data management infrastructure that can both manage participant activities and capture data to evaluate the intervention. Typical features required of the infrastructure for web-based intervention studies include: Health Information Portability and Accountability Act (HIPAA) alignment; safeguards to prevent data loss; a trackable audit trail of data additions and edits; controlled user access, routine backup of stored data; participant access to technical support; and real-time monitoring of participant progress in study activities (Embi & Payne, 2009; Mohr et al., 2014).

Research Electronic Data Capture (REDCap™) is a secure web application for building and managing online surveys and databases (Harris et al., 2009; Vanderbilt University, 2018). REDCap is available at no charge to not-for-profit institutions and was thus available to our research team (Harris et al., 2009; Vanderbilt University, 2018). Our University's REDCap instance is implemented using National Institute of Standards and Technology (NIST 800) security policies, procedures, and guidelines, aligning it with the HIPAA and including protections such as regular data backups, access controls, and intrusion prevention (National Institute of Standards and Technology, 2018). REDCap includes an application programming interface (API) that enables other software to interoperate with REDCap by programmatically exporting data from and importing data to REDCap.

Despite the common need for research teams to develop technology infrastructures for web-based interventions and to test their effectiveness, few guidelines are available to help accomplish

this task. The purpose of this paper is to describe the development and implementation of a REDCap-based data management infrastructure for an interactive and fully web-based therapeutic intervention.

WISER Intervention

Writing to Improve Self-in-Relationships (WISER) is a four-session asynchronous online intervention for emerging adults in troubled intimate relationships. Emerging adults are young people between the ages of 18 and 250 (Arnett, 2000). Emerging adulthood is considered a unique development period between adolescence and young adulthood and is marked by frequent changes in romantic partners, work and education goals, and residences (Arnett, 2000), WISER targeted to this age group because this development period is a time of exploration and experimentation with intimate partner relationships. We defined troubled relationships broadly to include any relationships with intimate partners that cause distress, anxiety, or unhappiness.

The WISER intervention is described in detail elsewhere (Draucker, Martsolf, Crane, Romero, & McCord, 2017). Briefly, the intervention is based on expressive writing techniques (Pennebaker & Chung, 2011) and narrative therapy principles (White & Epston, 1990). Narrative therapy is based on the assumption that individuals need not be defined by their problems and can re-author their troubled life narratives to be more fulfilling (White & Epston, 1990). In WISER, story-writing is used to help participants examine their troubled relationships and explore ways they could make their relationships more satisfying. For each session, participants access the study website to: (1) receive information about troubled relationships through written material and videos of actors playing emerging adults; (2) write a story reflecting their own troubled relationship(s); and (3) receive a personalized response from a peer advisor that reflects on important elements of their story, encourages further exploration, and introduces the next session. Peer advisors are emerging

adults (and thus close in age to the participants) who had a college degree in a health or wellness discipline. The peer advisors for the feasibility study were graduate students or recent alumni known to the investigators or recommend by colleagues. The investigators trained and closely supervised peer advisors to write the personalized responses based on narrative therapy tenets (White & Epston, 1990). The participants completed each session on their own time and on their own electronic devices; we asked them to complete one session per week.

We conducted a pilot study of WISER with a convenience sample of 14 students between the ages of 18 and 25 who were attending classes at the investigators' university. We easily recruited University students for a convenience sample using study announcements placed around campus and by study team members at tables setup in the university's campus center. In addition, the college counseling center was available in the event that the intervention caused psychological distress for any participant, although this did not occur. We collected outcome measures of relationship satisfaction and aggression at baseline, immediately post-intervention, and in a follow-up six weeks later. The Institutional Review Board at Indiana University reviewed and approved the WISER pilot study. Results of the pilot study are published separately (Draucker et al., 2018).

Methods

The data management infrastructure for the WISER intervention pilot study consisted of two components: a website for presentation of the intervention and participant account management and a REDCap project for data capture and storage. REDCap API connected these two components using HTML links and data exchanges. In general, participant-centered functions, such as orientation to the intervention, intervention sessions, and video presentations were managed through the website. We used REDCap for most data collection and storage including screening participants, collecting demographics, and completing measures pre- and post-intervention. In addition, we used

REDCap to facilitate online interactions between participants and peer advisors, manage participant access to the intervention, send notifications to study team members when tasks needed to be completed, and monitor participant progression through the intervention. Throughout the website and WISER written materials, the program directed participants to contact the research team using a team email address, if they had technical problems or other issues. Emails sent to the team email address were automatically forwarded to the project manager and principal investigator to ensure that concerns were addressed in a timely manner.

We developed the website using a standard Linux/Apache/MySQL/PHP (LAMP) stack to provide web server, server scripting, and database features. The website used participants' REDCap study IDs and email addresses to manage their accounts and to request and store their data. One key part of the technical solution was PHPCap, a server scripting library for accessing the REDCap API that was written in PHP by members of the Indiana University Pervasive Technology Institute (Mullen & Arenson, 2017). PHPCap provided reliable and simplified methods for requesting and writing data and/or files with the REDCap API.

Figure 1 diagrams the flow of the WISER intervention and its data management infrastructure. To explain further, the WISER intervention public webpage informed potential participants about the intervention, introduced the study team, and provided a registration link. After choosing to register, potential participants were directed via the REDCap public survey URL through a series of REDCap surveys (accomplished via the REDCap survey queue) that automatically generated a study ID. The first survey was the eligibility screening form, the second was the consent form, and the subsequent surveys were the demographic and pre-intervention baseline measures. To maintain a consistent visual experience, all REDCap surveys had a WISER intervention graphic header.

Participants who were ineligible or declined to participate were directed to a REDCap survey

(via the REDCap survey queue) that confirmed why the participant was not moving forward and, if applicable, asked why they had declined to participate. Participants were then directed back to a WISER intervention webpage that thanked them for their interest and provided resources for individuals in troubled relationships. This flow avoided participants seeing the potentially confusing REDCap survey completion messages. Participants who successfully completed the on-study process were directed back to the WISER intervention website and guided through the process of creating a password and setting security questions. We used the same email address participants had provided in the on-study process as the website login ID to facilitate the interaction between REDCap and the WISER website. In the event participants or a forgotten or compromised password, participant could reset their own password on the WISER intervention website without contacting the study team, provided they correctly answered the security questions.

The study team received notification through REDCap that a participant enrolled upon completion of baseline measures. Upon receiving this notification, a study team member assigned a peer advisor and gift card claim code (incentive for completing baseline measures) to the participant in REDCap. Assigning the peer advisor triggered an automated REDCap survey invitation to the participant with a pre-written message from the advisor. In addition, we attached the advisor's photograph and a brief biographical statement in the survey. Similarly, assigning the gift card claim code triggered a different automated REDCap survey invitation that included their gift card claim code and instructions for redemption. After viewing these surveys, participants were directed back to the WISER website or the website for claiming their gift card, again avoiding potentially confusing REDCap survey completion messages.

After setting up their access to the WISER website, the WISER intervention was immediately available to participants. Participants were first instructed to download written materials about the intervention, and then directed to the webpage for the first WISER session. Each

session's webpage included a video for participants to view and instructions for writing their story for that session. Participants were able to write their story using any software but we asked them to save the file in Microsoft Word or PDF format. Participants submitted stories by uploading the file on the WISER session's webpage. REDCap API saved the stories directly saved in REDCap.

When a participant uploaded a story, peer advisors and other study team members received an email notification from the WISER website. The peer advisor then accessed REDCap to read the story and write a personalized response using a REDCap notes box. Completing the entry in the notes box field triggered an automated survey invitation to the participant with a pre-written email message from their advisor and the personalized response attached as the survey. After reading the response, the participant was directed back to the WISER website to continue with the next session. The next session only became available after the advisor response was completed and the participant had viewed it. Participants could review their advisor's responses at any time on the session's webpage.

Participants progressed through the WISER intervention until they completed the fourth session and viewed their peer advisor's final response. Reading this response triggered two automated survey invitations. One invitation was to complete the immediate post-intervention outcome measures. The second invitation, sent 60 days later, was to complete the follow-up outcome measures. REDCap survey queue managed the surveys at both timepoints. Team members received a survey notification when participants completed either outcome measures, ensuring the appropriate transmission of the gift card (incentive for completing the outcome measures) to participants.

The REDCap database was setup with one arm and seven separate events: enrollment, session 1, session 2, session 3, session 4, off-study, and follow-up. Participant access to the WISER website was controlled by the 'Active Participant' field within the enrollment event in REDCap. Disabling this field blocked participants from logging into to the WISER website. Registration to the

WISER pilot study was available at any time via the link on the WISER public webpage. When the study team decided to halt new registrations, a message replaced the link indicating that registration was closed and indicating when registration would re-open.

Each peer advisor manually monitored participant progress using the REDCap record status dashboard. When participants stalled (i.e. did not upload their stories within a week), peer advisors were able to compose personalized reminder messages via survey invitations in REDCap. These messages encouraged participants to continue with WISER, reminded them of the progress they had made so far, and redirected them back to the WISER webpage. The survey attached to these email messages provided an opportunity for participants to withdraw from the WISER intervention if they wished. Participants who withdrew were asked why they chose to stop participating in WISER.

Results

We developed the WISER data management infrastructure using available resources; the system functioned well during the pilot study with two minor exceptions. First, participants who registered for WISER and completed the baseline measures but did not immediately setup their access to the WISER intervention website did not have a way to return later to finish setting up their password and security questions. We addressed this problem by developing a process for manually sending a URL to the affected participants that enabled them to finish setting up access to the website.

Second, at one random time point the REDCap automatic survey invitation feature triggered unexpected transmission of surveys to participants. This incident was reported for further analysis and monitoring to the university's REDCap support team. Although the problem was not reproducible, it likely began when a research team member later updated a calculated field on a REDCap survey and data quality checks were performed that affected existing records which, in

turn, triggered logic that automatically sent out survey invitations.

In addition, experimentation and ongoing collaboration amongst team members was necessary to determine the most effective infrastructure flow. For example, a limitation of REDCap is the inability to send emails other than automated survey notifications to study team members. This limitation meant that REDCap could not trigger notifications when participants failed to complete an activity within REDCap, i.e. by not uploading their story. After initially trying to send reminders with the assistance of an automated job script (i.e. a 'cron' job) that ran every day on the WISER intervention website server, the study team decided that a more personalized approach to stalled participants would be more effective. Thus, peer advisors sent stalled participants personalized survey invitations in REDCap that contained specific reminder messages.

Discussion

The WISER data management infrastructure was so successful in supporting the WISER intervention that it will also be used in future larger trials of the WISER intervention. Participants were able to move through the WISER intervention seamlessly, completing study activities and sending communications to their peer advisors online at their leisure. Moreover, the centralized storage of participant data in REDCap enabled study team members to use REDCap's record status dashboard to easily monitor and manage participants' progress through the intervention.

The multi-disciplinary technology team had expertise with REDCap, website design, server scripting, and nursing informatics, facilitating the creative development of the infrastructure. Moreover, some were members of the academic institution's REDCap support team. While overall, we had a positive experience with the advanced REDCap functionality and this REDCap-based infrastructure, based on our experiences nurse researchers using REDCap's automated survey invitations with therapeutic interventions should use caution. We recommend sending out weekly

monitoring of the REDCap survey invitation log to verify the automated invitations.

Conclusions

REDCap's functionality is continually being developed and expanded, which allows nurse researchers to use it in increasingly novel ways. Through its ability to facilitate confidential, secure interactions with participants, as well as to manage data and participant progression, REDCap is a powerful and cost-effective tool for supporting web-based therapeutic intervention research.

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Figure Legend

Figure 1: WISER Intervention and Data Management Flowchart

Figure 1